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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,722	03/12/2002	Nobuo Ishiyama	2554-9	2663

23117 7590 01/13/2005  
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EXAMINER

KOSAR, ANDREW D

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 01/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicati n No.

09/913,722

Applicant(s)

ISHIYAMA ET AL.

Examiner

Andrew D Kosar

Art Unit

1654

-- The MAILING DATE of this communication appears n the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) 2-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/17/01;9/28/04</u> . | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Claims 1-34 are pending.

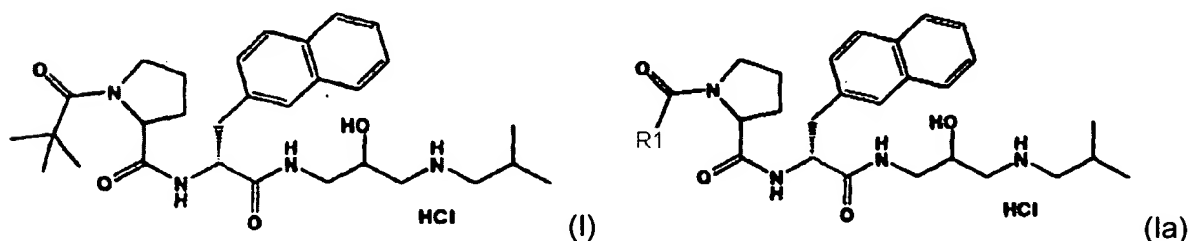
#### *Election/Restrictions*

Claims 5-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on December 7, 2004. Claims directed to the process of making or using the product(s), which are withdrawn from consideration as a result of a restriction requirement, will be handled pursuant to the procedures set forth in the previous Office Action.

Applicant's election of Group I in the reply filed on December 7, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The restriction is still deemed proper and made FINAL.

Applicants elected the species (I), readable upon Group I, and claim 1:

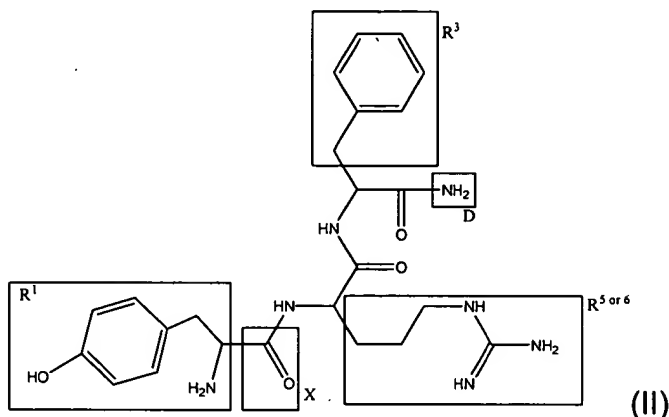


The Examiner further examined the claims of Group I where R<sup>1</sup> (*tert*-butyl, as elected) is variable, according to claims 2-4, (Ia).

The Examiner has found the species (I) and the genus (Ia) to be free of the art.

The Examiner elected the following species readable upon the generic claim:

Tyr-Arg-Phe-NH<sub>2</sub> (II):



R<sup>2</sup> and R<sup>4</sup> are H, R<sup>5</sup> or R<sup>6</sup> is H, n = 0.

The compound reads upon claim 1.

Claims 2-4 are withdrawn from consideration as not readable upon the species elected by the Examiner.

### **Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by WO 93/04081 ('081), (PTO-1449, August 2001).

The claims are broadly drawn to compounds which may be peptides, wherein the amino acid comprising R<sup>3</sup> may not be glycine (*vida infra* based upon "\*" indicating an asymmetric center).

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R<sup>1</sup> broadly defines one embodiment as 'substituted alkyl'. Given the broadest reasonable interpretation, in conjunction with X = CO, it includes an amino acid, eg.- Tyrosine, wherein R<sup>1</sup> is a 1-amino-2-(4-hydroxyphenyl)ethyl and X is CO (see compound (II) *supra*).

R<sup>5</sup> or R<sup>6</sup> broadly define one embodiment as 'substituted alkyl' and the other may be a proton. Given the broadest reasonable interpretation, this includes the side chain of arginine, an alkyl chain which is substituted at the terminus.

D defines one embodiment as 'unsubstituted amino', e.g.- NH<sub>2</sub>.

R<sub>3</sub> is broadly defines one embodiment as 'substituted alkyl'. Given the broadest reasonable interpretation, this includes the side chain of phenylalanine, a phenyl-substituted methyl moiety.

Because '081 teaches the embodiment presented *supra* (II) (Page 58, '081), claim 1 is anticipated.

### ***Allowable Subject Matter***

As indicated *supra* the elected species (I) and compounds of the generic formula (Ia) are free of the prior art.

The following is a statement of reasons for the indication of allowable subject matter: The closest prior art, US Patent 5,439,930 ('930), 5,525,623 ('623); and WO 93/04081 ('081); and RP Nargund, et al.; and C Walpole, et al. neither suggest or provide motivation to make, alone or in combination, compounds (I) or (Ia), *supra*.

'930 teaches N-acylated Proline compounds, but does not teach or suggest the instantly claimed compounds (I) or (Ia).

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'623 teaches dipeptides, but does not teach or suggest the instantly claimed compounds (I) or (Ia).

'081 teaches the compound (II), *supra*, and related analogs, but does not teach or suggest the instantly claimed compounds (I) or (Ia).

Nargund teaches the compound MK-0667 and other GHS compounds, but does not teach or suggest the instantly claimed compounds (I) or (Ia).

Walpole teaches the compound SDZ NKT 343 and related analogs, but does not teach or suggest the instantly claimed compounds (I) or (Ia).

***Prior Art of Record***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US PG PUBs 2002/0161240 A1 and 2002/0137686 A1; US Patents 615,0527, 6147189, 6133456, 6100069, 6100047, 6084066, 5965698, 5952465, 4560506, 5869671, 4626545, 4927809, 4093713, 4250192, and 4766110.


**NO CLAIMS ARE ALLOWED.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 8am-430pm.

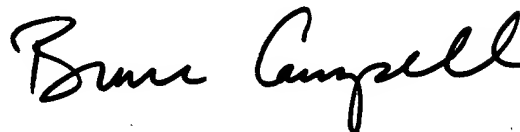
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571)272-0974. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Andrew D. Kosar, Ph.D.  
Patent Examiner  
Art Unit 1654



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